

**510(k) Summary**

Date Prepared: 4 December 2008

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MAR 26 2009

**Contact:** Bret M. Berry  
Member-Manager

Common or Usual Name:	Spinal Fixation Device
Proposed Proprietary or Trade Name:	Reliance Spinal Screw System
Classification Name:	Spinal Intervertebral Body Fixation Orthosis (per 21 CFR 888.3060) Spinal Interlaminar Fixation Orthosis (per 21 CFR 888.3050) Spondylolisthesis Spinal Fixation Device System and Pedicle Screw System (per CFR 888.3070)
Product Code:	KWP, KWQ, MNH, MNI

**Substantial Equivalence**

The **Reliance Spinal Screw** is substantially equivalent to the legally marketed Medtronic TSRH Spinal System (K880215, K072429), Medtronic CD Horizon (K961633, K063670), DePuy Expedium Spine System (K041119, K081252), DePuy Isola Spinal System (K905184, K022285), DePuy Viper Spine System (K061520, K073562), DePuy MOSS Miami Spinal System (K933881, K030383), Pioneer Surgical Quantum Spinal System (K070973, K080518), K2M Range Spinal System (K080792), K2M Denali Spinal System (K042635, K052404), K2M Mesa Spinal System (K052398), Interpore Cross Synergy Spinal System (K940631, K041449), Stryker Xia Spinal System (K984251, K080928), X-Spine Capless Pedicle Screw System (K052847, K072282), Synthes Pangea (K052123). The **Reliance Spinal Screw** is equivalent to these commercially available devices in terms of material, intended use, levels of attachment, size range, and strength.

**Device Description**

The **Posterior RELIANCE Spinal Screw System** consists of longitudinal rods, monoaxial screws, polyaxial screws, reduction screws, cannulated poly axial screws, cannulated reduction screws, hooks, reduction hooks, set screws, transverse connectors. The **Anterior RELIANCE Spinal Screw System** consists of two spinal rods, monoaxial screws, staples, and set screws. The Anterior RELIANCE staples and screws are intended to be attached to the lateral aspect of the vertebral bodies from T5 to L4, and SHOULD NOT be attached to the anterior aspect. Furthermore, only Titanium components should be used anteriorly. (See Precautions section.)

The **RELIANCE Spinal Screw System** components are available in titanium alloy conforming to ASTM F-136 specifications as well as stainless steel conforming to ASTM F-138 specifications. Furthermore, various rods of the **RELIANCE Spinal Screw System** are available in Cobalt Chrome conforming to ASTM F-75 specifications. Components of the differing diameter rod systems are NOT interchangeable. The components of one material should not be used with components of another material, with the exception that the Cobalt Chrome rods may be used with titanium alloy implants. The extension tabs on the reduction screw and hook components are intended to be removed intraoperatively.

#### **Intended Use/Indications for Use**

The **RELIANCE Spinal Screw System** is a pedicle screw systems intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine: degenerative spondylolisthesis with objective evidence of neurological impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudarthrosis).

The **RELIANCE Spinal Screw System** is also indicated for pedicle screw fixation for the treatment of severe spondylolisthesis (Grades 3 and 4) of the L5-S1 vertebra in skeletally mature patients receiving fusion by autogenous bone graft having implants attached to the lumbar and sacral spine (L3 to sacrum) with removal of the implants after the attainment of a solid fusion.

When used posteriorly, the **RELIANCE Spinal Screw System** is also a hook and sacral/iliac screw fixation system of the noncervical spine indicated for, spondylolisthesis, trauma (fracture and/or dislocation), spinal stenosis, deformities (scoliosis, lordosis and/or kyphosis), tumor, and previous failed fusion (pseudarthrosis). Levels of fixation are for the thoracic, lumbar and sacral spine.

The **RELIANCE Spinal Screw System** when used with staples and two rods as an anterior thoracic/lumbar screw fixation system, is indicated for spondylolisthesis, trauma (fracture and/or dislocation), spinal stenosis, deformities (scoliosis, lordosis and/or kyphosis), tumor, and previous failed fusion (pseudarthrosis).

When used in a percutaneous, posterior approach with MIS Instrumentation, the **RELIANCE Spinal Screw System** components are intended for noncervical pedicle fixation and nonpedicle fixation for the following indications: spondylolisthesis; trauma (i.e., fracture or dislocation); spinal stenosis; curvatures (i.e., scoliosis, kyphosis, and/or lordosis); tumor; pseudoarthrosis; and failed previous fusion in skeletally mature patients.

#### **Non-Clinical Testing**

The **RELIANCE Spinal Screw System** has undergone Non-Clinical Testing including Static Compressive, Static Torsion, and Dynamic Compressive in accordance with ASTM F1717.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Reliance Medical Systems, LLC  
% Mr. Bret M. Berry  
Member-Manager  
2647 Cassowary Circle  
Sandy, Utah 84092

MAR 26 2009

Re: K081978

Trade/Device Name: Reliance Spinal Screw System  
Regulation Number: 21 CFR 888.3070  
Regulation Name: Pedicle screw spinal system  
Regulatory Class: II  
Product Code: MNI, MNH, KWQ, KWP  
Dated: March 23, 2009  
Received: March 24, 2009

Dear Mr. Berry:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

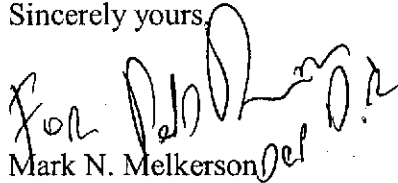
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Mark N. Melkerson", is written over the typed name.

Mark N. Melkerson

Director  
Division of General, Restorative  
and Neurological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

**Indications for Use**510(k) Number (if known): K081978Device Name: Reliance Spinal Screw System**Indications for Use:**

The Reliance Spinal Screw System is a pedicle screw systems intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine: degenerative spondylolisthesis with objective evidence of neurological impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudarthrosis). The Reliance Spinal Screw System is also indicated for pedicle screw fixation for the treatment of severe spondylolisthesis (Grades 3 and 4) of the L5-S1 vertebra in skeletally mature patients receiving fusion by autogenous bone graft having implants attached to the lumbar and sacral spine (L3 to sacrum) with removal of the implants after the attainment of a solid fusion.

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Prescription Use X  
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF  
NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)  
(Division Sign-Off)

**Division of General, Restorative,  
and Neurological Devices**

510(k) Number

16081978